UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF NORTH CAROLINA

No. 1:16-cv-01303-TDS-JEP
(Consolidated)

JOHNATHAN HIRTENSTEIN, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. CEMPRA, INC., et al., Defendants.	CLASS ACTION Judge Thomas D. Schroeder Magistrate Judge Joi Elizabeth Peake CONSOLIDATED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

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INTRODUCTION AND OVERVIEW

1. Lead Plaintiffs Charles Craig Janies, Robert F. Colwell, Jr. and Jennifer Colwell, hereby bring this action on behalf of themselves and all other persons or entities who purchased or otherwise acquired the common stock and call options of Cempra, Inc., ("Cempra" or the "Company") between July 7, 2015 and November 4, 2016, inclusive (the "Class Period"), and were damaged thereby (the "Class"). Excluded from the Class, as defined below, are Defendants, present or former executive officers of Cempra and their immediate family members (as defined in 17 C.F.R. §229.404, Instructions (1)(a)(iii) and (1)(b)(ii)). Plaintiffs seek to recover damages caused by Defendants' violations of §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), and Rule 10b-5 promulgated thereunder.

2. Plaintiffs allege the following based upon personal knowledge as to themselves and their own acts and upon information and belief as to all other matters. Plaintiffs' information and belief is based upon, *inter alia*, the independent investigation of their attorneys. This investigation included, but was not limited to, a review and analysis of: (i) the results of Cempra's clinical trials of solithromycin (CEM-101), with the proposed name of Solithera; (ii) Cempra's public filings with the U.S. Securities and Exchange Commission ("SEC"); (iii) transcripts of Cempra's public conference calls; (iv) the U.S. Food & Drug Administration ("FDA") Antimicrobial Drugs Advisory Committee meeting materials; (v) Cempra's press releases; (vi) independent media reports regarding Cempra; (vii) economic

analyses of Cempra's stock price movement and pricing and volume data; and (viii) other publicly-available material and data identified herein.

3. Counsel's investigation of the facts underlying this action continues, and counsel further believes that relevant facts are known only by Defendants or are exclusively within their custody or control. Plaintiffs believe that additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

4. Cempra is a clinical-stage biopharmaceutical company that develops antibiotics for the treatment of infectious diseases. According to the Company, Cempra's lead product, solithromycin, is being developed in oral capsule, intravenous ("IV") and suspension formulations for the treatment of community-acquired bacterial pneumonia ("CABP"), as well as for the treatment of gonorrhea and for other indications.

5. CABP is the leading cause of death due to infection in the United States, with a reported five to ten million cases per year. CABP is increasingly resistant to the currently-approved class of antibiotics called macrolides, which is the most frequently prescribed type of antibiotic used to treat respiratory tract infections. Antibiotic resistance is a complex, emerging problem with potentially devastating consequences for public health. Solithromycin, Cempra's lead asset, is a fourth-generation fluoroketolide macrolide-class antibiotic for the treatment of CABP which is not supposed to have the resistance problem of older macrolides.

6. During the Class Period, Cempra was in the late stages of its clinical development program of solithromycin to treat CABP. In August 2015, the FDA granted the

drug Fast Track designation for solithromycin IV and capsules for the treatment of CABP. The FDA's Fast Track program is designed to facilitate the development and expedite the review of new drugs intended to treat serious or life-threatening conditions and have the potential to address unmet medical needs. On May 1, 2016, Cempra completed and submitted its New Drug Applications ("NDAs") for solithromycin to the FDA for the treatment of CABP. Because solithromycin had been granted qualified infectious diseases product ("QIDP") designation, the NDAs were entitled to eight-month priority reviews, resulting in Prescription Drug User Fee Act ("PDUFA") dates of December 27 and December 28, 2016 for the oral and IV NDAs, respectively.

7. Throughout the Class Period, Defendants violated the federal securities laws by disseminating false and misleading statements to the investing public regarding the safety of solithromycin. Specifically, beginning on July 7, 2015, and despite their knowledge of studies to the contrary that were either completed prior to the Class Period or were ongoing during the Class Period, Defendants publicly claimed that: (i) solithromycin was backed by "compelling" safety data; (ii) increased liver enzymes suffered by patients in the Company's solithromycin clinical trials were asymptomatic (not associated with evidence of liver toxicity or liver injury); (iii) they had seen no evidence of liver hypersensitivity or injury during clinical trials; (iv) solithromycin was not associated with liver toxicity; and (v) solithromycin had differentiated itself as superior to Ketek with respect to liver toxicity and injury risk. In truth, in completed Phase 3 studies of solithromycin, at least eight patients taking the drug had in fact experienced liver toxicity and liver injury (all of whom also

experienced significant increases in liver enzymes). Further, in Phase 1 and Phase 2 studies that had been completed prior to the Class Period or were otherwise ongoing during the Class Period, at least six additional patients taking solithromycin had experienced liver toxicity and liver injury (all of whom also experienced significant increases in liver enzymes). Defendants' Class Period conduct had its intended effect, with Cempra's stock trading at artificially-inflated prices during the Class Period, reaching a high of $32.81 per share on November 25, 2015.

8. On November 2, 2016, the FDA released briefing documents for solithromycin's FDA Advisory Committee ("AdCom") meeting on November 4, 2016. FDA Advisory Committees provide independent, expert advice to the FDA on complex, and often controversial, scientific, technical, and policy issues regarding, *inter alia*, NDAs. The FDA's November 2, 2016 briefing materials analyzed Cempra's clinical development program for solithromycin to treat CABP and other conditions, and provided the following summary regarding the drug's association with hepatotoxicity and liver injury:

> In the solithromycin development program to date, a range of patterns of liver injury associated with exposure to solithromycin were observed. There was a spectrum of both hepatocellular and cholestatic signatures of hepatotoxicity, in one case accompanied by eosinophilia and suggesting hypersensitivity as a mechanism for liver injury. These findings were noted among a relatively small number of patients treated with solithromycin for CABP (n=920), normal healthy volunteers exposed to the drug in PK studies, and a small number of patients administered solithromycin in studies of other conditions. We conclude that these findings comprise a genuine liver injury signal.

9. As a result of the FDA's release of the briefing materials regarding solithromycin's association with liver injury, the price of Cempra stock dropped $11.35 per

share to close at $7.30 per share on November 2, 2016, a one-day decline of nearly 61% on volume of 20.7 million shares.

10. Trading in Cempra's stock was halted during the AdCom hearing on November 4, 2016. While the AdCom voted narrowly in favor of solithromycin's approval, slides released during the AdCom hearing contained additional information concerning the drug's negative impact on the liver. When trading resumed on Monday, November 7, 2016, the price of shares of Cempra stock fell an additional $0.70 per share, or over 9%, to close at $6.85 per share on volume of 13.6 million shares.

11. Finally, on December 29, 2016, Cempra announced the details from a Complete Response Letter ("CRL") issued by the FDA regarding solithromycin's NDAs for CABP. While the FDA had no further request on solithromycin's efficacy, the FDA required additional clinical safety information to adequately characterize the risk of solithromycin's hepatotoxicity. The FDA recommended a comparative study to evaluate the safety of solithromycin with approximately 9,000 CABP patients exposed to solithromycin. The FDA also indicated that even in the absence of a case of Hy's Law or another form of serious drug induced liver injury ("DILI"), if solithromycin was approved, the drug's label would need to include adequate information about the potential for hepatotoxicity. The FDA required a comprehensive plan for post-marketing safety assessment, including an enhanced pharmacovigilance program. On this news, the price of shares of Cempra stock fell another 57%, from $6.10 per share to $2.60 per share on volume of 21.4 million shares.

12. As a result of Defendants' false and misleading statements, Cempra common stock traded at artificially-inflated prices during the Class Period. However, after the above revelations seeped into the market, the price of the Company's common stock dropped over 92% from its Class Period high, causing economic harm and hundreds-of-millions of dollars in damages to Class Members.

JURISDICTION AND VENUE

13. The claims asserted herein arise under and are pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)), and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

14. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

15. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b) because a significant portion of Defendants' actions, and the subsequent damages, took place within this District.

16. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mail, interstate telephone communications and the facilities of national securities exchanges.

PARTIES

Plaintiffs

17. **Charles Craig Janies**: Plaintiff Charles Craig Janies is a resident of Houston, Texas. As set forth in the certification already on file with the Court (Dkt. No. 20-2), Mr.

Janies purchased Cempra common stock, as well as call options on Cempra common stock, on the NASDAQ Stock Market ("NASDAQ") during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

18. **Robert F. Colwell, Jr.**: Plaintiff Robert F. Colwell, Jr. is a resident of Bennington, Nebraska, and is married to plaintiff Jennifer Colwell. As set forth in the certification already on file with the Court (Dkt. No. 20-2), Mr. Colwell purchased Cempra common stock, as well as call options on Cempra common stock, on the NASDAQ during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

19. **Jennifer Colwell**: Plaintiff Jennifer Colwell is a resident of Bennington, Nebraska, and is married to plaintiff Robert F. Colwell, Jr. As set forth in the certification already on file with the Court (Dkt. No. 20-2), Ms. Colwell purchased Cempra common stock on the NASDAQ during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

20. Plaintiffs Charles Craig Janies, Robert F. Colwell, Jr. and Jennifer Colwell are referred to herein, collectively, as "Plaintiffs."

Defendants

21. **Cempra**: Defendant Cempra is a Delaware corporation that describes itself as a clinical-stage pharmaceutical company focusing on the development of anti-infective drugs for acute care in community settings to meet critical medical needs in the treatment of infectious diseases. At all relevant times, the Company's lead product was solithromycin.

During the Class Period, the Company generated no revenue from the sale of solithromycin. The Company's principal offices are located at 6320 Quadrangle Drive, Suite 360, Chapel Hill, North Carolina. During the Class Period, the Company's common stock traded in an efficient market on the NASDAQ under the symbol "CEMP."

22. **Prabhavathi Fernandes**: Defendant Prabhavathi Fernandes, Ph.D. ("Fernandes") served as the Company's Chief Executive Officer ("CEO"), President and member of the Board of Directors from the Company's founding in November 2005 and throughout most of the Class Period. On December 12, 2016, the Company disclosed that Fernandes had "retired" from the Company effective immediately, but would continue to be paid under contract as a consultant to Cempra for one year. Previously, Cempra's April 6, 2016 Proxy Statement stated that Fernandes was a co-founder of Cempra and emphasized her "experience in senior leadership roles in small and large pharmaceutical organizations."

23. Prior to and during the Class Period, Fernandes was responsible for the content and approval of Cempra's Code of Ethics for Principal Executive Officer and Senior Financial Officers ("Code of Ethics") and Code of Conduct. According to the Code of Ethics, during the Class Period Fernandes was required to ensure the "full, fair, accurate, timely and understandable disclosure in the reports and documents filed by the Company" with the SEC "and in other public communications made by the Company." The Code of Ethics also required Fernandes to "act honestly, ethically, in good faith, responsibly, with due care, competence and diligence, and without misrepresenting material facts or allowing [her] independent judgment to be subordinated." Cempra's Code of Conduct required

Fernandes, when interacting with the investing public, to ensure that all disclosures of public communications made by Cempra are "full, fair, accurate, timely and understandable."

24. Fernandes made or had authority over the content and dissemination of the false and misleading statements set forth herein at ¶¶58-59, 61-65, 67, 69, 75-77, and is liable for those false statements and omissions. Fernandes is also a control person of Cempra within the meaning of §20(a) of the Exchange Act.

25. **Mark W. Hahn**: Defendant Mark W. Hahn ("Hahn") served as the Company's Executive Vice President and Chief Financial Officer ("CFO") at all relevant times. Prior to joining Cempra, Hahn served as CFO of Athenix Corp, an agricultural biotechnology company.

26. Prior to and during the Class Period, Hahn was responsible for the content and approval of Cempra's Code of Ethics and Code of Conduct. According to the Code of Ethics, during the Class Period Hahn was required to ensure the "full, fair, accurate, timely and understandable disclosure in the reports and documents filed by the Company" with the SEC "and in other public communications made by the Company." The Code of Ethics also required Hahn to "act honestly, ethically, in good faith, responsibly, with due care, competence and diligence, and without misrepresenting material facts or allowing [his] independent judgment to be subordinated." Cempra's Code of Conduct required Hahn, when interacting with the investing public, to ensure that all disclosures of public communications made by Cempra are "full, fair, accurate, timely and understandable."

27. Hahn made or had authority over the content and dissemination of the false statements and omissions set forth herein at ¶¶59, 69, 73-74, and is liable for those false statements and omissions. Hahn is also a control person of Cempra within the meaning of §20(a) of the Exchange Act.

28. **David W. Oldach**: Defendant David W. Oldach, M.D. ("Oldach") served as the Company's Chief Medical Officer ("CMO") at all relevant times. Prior to joining Cempra, Oldach directed clinical research at Gilead Sciences, Inc., where his experience included drug development and execution and study protocol development and execution. Between November 9, 2015 and December 11, 2015, Oldach sold 22,200 shares of Cempra common stock at prices between $27.78 per share and $30.33 per share, for total proceeds of nearly $654,000. The cost basis for these shares was approximately $51,000, resulting in an ill-gotten profit of approximately $603,000. Prior to the Class Period, Oldach did not report the sale of any Cempra common stock. Following the Class Period, Oldach also did not report the sale of any Cempra common stock.

29. Throughout the Class Period, Oldach was subject to the Company's Code of Conduct. Cempra's Code of Conduct required Oldach, when interacting with the investing public, to ensure that all disclosures of public communications made by Cempra are "full, fair, accurate, timely and understandable."

30. Oldach made or had authority over the content and dissemination of the false statements and omissions set forth herein at ¶¶60, 66, 68, 76, and is liable for those false

statements and omissions. Oldach is also a control person of Cempra within the meaning of §20(a) of the Exchange Act.

31. Defendants Fernandes, Hahn and Oldach are referred to herein, collectively as the "Individual Defendants."

32. Defendants Cempra, Fernandes, Hahn and Oldach are referred to herein, collectively as "Defendants."

BACKGROUND AND PRE-CLASS PERIOD EVENTS

Cempra and Solithromycin

33. Cempra is a clinical-stage pharmaceutical company that was co-founded in 2006 by defendant Fernandes. The Company is focused on developing differentiated antibiotics for the treatment of bacterial infectious diseases, particularly respiratory tract infections and chronic staphylococcal infections.

34. Solithromycin, Cempra's lead product and single most important compound, was licensed from Optimer in March 2006. Solithromycin belongs to a class of antibiotics known as macrolides. Macrolides are the most frequently prescribed antibiotics to treat respiratory tract infections. Resistance to older macrolides, like Z-Pak or Zithromax, is on the rise with the level of resistance approaching or exceeding 50% in recent years. As a result, hospital visits have been more frequent and outpatient doctors have been resorting to the use of a fluoroquinolone, like Levaquin or Avelox, as first-line agents for CABP.

35. Many side effects are associated with the fluoroquinolones, including C. difficile colitis, tendonitis, Achilles tendon rupture, aortic aneurysm and retinal detachment.

In July 2016, the FDA approved safety labeling changes for fluoroquinolones to enhance warnings about their association with disabling and potentially permanent side effects and to limit their use in patients with less serious bacterial infections. Essentially, the FDA stated that the risks outweigh the benefits for bronchitis, sinusitis and urinary tract infections. While pneumonia was not specifically included in the warning, such a black box warning was expected to affect physicians' prescribing pattern in CABP cases. A black box warning appears on a prescription drug's label and is designed to call attention to serious or life-threatening risks. Consequently, macrolides are the preferred first-line treatment for CABP due to their targeted spectrum and their lack of such serious side effects associated with fluoroquinolones. Long QT syndrome and related sudden death, however, are examples of the most recent serious side effects associated with macrolides. Most CABP patients are the elderly and are most commonly associated with heart disease. Therefore, Long QT syndrome can be serious in these patients if it is caused by their antibiotic to treat CABP, which is already placing stress on these elderly patients' lungs and cardiovascular system.

The Market for Solithromycin and Ketek

36. Cempra described solithromycin in its press releases as "a highly potent next-generation macrolide, the first fluoroketolide, which has potent activity against most macrolide-resistant strains." The resistance rate for solithromycin for common bacteria was expected to be less than other older macrolides, because bacteria must mutate at three sites to become resistant to the drug, compared to one or two sites for older macrolides. In other words, the drug was promoted as able to withstand resistance longer than the current

macrolide therapies, and even if it did not, it would be one of the only solutions to CABP for the nearly 50% of people who have antibiotic resistance. CABP is the seventh largest cause of death in the United States. During the Class Period, the most bullish estimates of Cempra's sales for the treatment of CABP worldwide were up to ***$2 billion*** per year if solithromycin were approved by the FDA.

37. Because of the serious side effects of fluoroquinolones and the resistance levels to older macrolides, companies have long sought to develop a drug with fluoroquinolone-like efficacy and macrolide-class safety without the resistance problem. The first drug to have earned this distinction was telithromycin, known under the brand name of Ketek, a third-generation macrolide and first ketolide antibiotic. In 2004, the FDA approved Ketek as an anti-microbial agent that purportedly circumvented antibiotic resistance. The FDA approved Ketek for CABP, acute exacerbation of chronic bronchitis ("AECB") and acute bacterial sinusitis ("ABS"). Shortly after its approval, however, Ketek was linked to dozens of cases of reversible visual disturbances, loss of consciousness, myasthenia gravis (a neurological disorder characterized by improper muscle regulation), and severe liver injury which resulted in liver failure, death and liver transplant. These safety issues prompted two Congressional investigations into the FDA's approval of the compound and accusations from FDA insiders that the agency stifled concerns over the drug voiced by its own reviewers and dismissed suspicious clinical data that were later shown to be fraudulent. Ultimately, the investigations led to upheavals in division leadership and staffing at the FDA. On February 12, 2007, the FDA and the sponsor, Sanofi S.A., agreed to drop two respiratory indications and keep

CABP, with a black box warning highlighting a high risk of potential liver injuries and contraindicating the drug for certain patients.

38. Recognizing that an inability to differentiate solithromycin from Ketek would adversely impact its revenue-generating capabilities prior to and throughout the Class Period, Defendants touted solithromycin as safer than Ketek. With solithromycin, Cempra constructed essentially the same drug but without the elements it claims were responsible for Ketek's side effects. Specifically, as a fluoroketolide, solithromycin includes an aminophenyl group with 1, 2, 3-triazole ring (instead of the pyridine attached to an imidazole ring in Ketek) to eliminate the off-target binding to the nicotinic acetylcholine receptors which purportedly caused Ketek's serious visual, muscle and liver problems.

Phases of Clinical Investigation

39. Clinical trials progress through three distinct phases of clinical investigation in humans, identified as Phase 1, Phase 2 and Phase 3, and are described by 21 C.F.R. §312.21. Phase 3 trials are the most significant for testing the efficacy and safety of a drug.

40. According to 21 C.F.R. §312.21, Phase 1 studies involve early safety testing and "are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness."

41. Phase 2 studies are "typically well controlled" exploratory studies "conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients

with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug." 21 C.F.R. §312.21(b).

42. Phase 3 studies are expanded studies "performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects." 21 C.F.R. §312.21(c).

43. Each phase of clinical testing attempts to gather more information on drug safety and efficacy in human subjects, and each phase requires an increase in the population size. Generally speaking, while Phase 1 studies typically focus on dose tolerance of a drug, Phase 2 studies focus both on dose tolerance and efficacy. Phase 3 studies focus on efficacy and safety.

Solithromycin's Development Program

44. Solithromycin, like other drugs, is subject to a series of pre-clinical and clinical trials to evaluate its effectiveness and safety for particular treatments prior to obtaining marketing approval. According to Cempra, its Phase 1 and Phase 2 clinical trials and pre-clinical studies showed a favorable safety and tolerability profile for solithromycin.

45. As disclosed in the Company's SEC filings, during one of Cempra's Phase 1 clinical trials for oral solithromycin, the FDA placed a partial clinical hold on the trial due to concerns over possible toxicity related to solithromycin. In April 2010, the FDA converted

the partial clinical hold into a full clinical hold. The FDA had concerns that solithromycin, as a fluoroketolide, may have similar toxicity issues as Ketek. Cempra assured investors that it addressed the FDA's concerns and it was allowed to proceed with the trial, which it successfully completed, but noted that the hold indicated possible scrutiny the FDA may apply to its NDAs due to the Ketek experience.

46. In its Phase 1 studies, Cempra's objective was to demonstrate the safety and tolerability of solithromycin, as well as to select the therapeutic dose after IV administration for its planned IV-to-oral trial. According to Cempra's 2015 Form 10-K, 20% of healthy subjects in its Phase 1 IV trial who received repeat-doses of intravenous solithromycin had asymptomatic and reversible Grade 4 elevations of alanine aminotransferase ("ALT"), a liver enzyme that is an indicator of liver damage or injury. Cempra noted that no clinically significant systemic adverse events were observed, except injection site pain in some subjects. Based on the study, Cempra selected a therapeutic dose of 400 mg administered intravenously once daily for up to seven days for its Phase 3 IV-to-oral trial with the option of stepping down to oral treatment of solithromycin when appropriate as decided by the physician based on decreased symptoms.

47. In its Phase 2 oral CABP trial, Cempra sought to evaluate the efficacy and safety of oral solithromycin compared to oral levofloxacin, one of the most widely prescribed antibiotics used to treat CABP, in 132 patients with CABP. The study demonstrated comparable efficacy to levofloxacin. With regard to safety, Cempra reported that 29.7% of patients had a treatment emergent adverse event ("TEAE"), compared with

45.6% of patients in the levofloxacin group. No patients discontinued the study due to a TEAE in the solithromycin group compared with 8.8% of patients in the levofloxacin group. Two solithromycin patients had a serious adverse event ("SAE"), both of which were determined to be unrelated to solithromycin. Seven levofloxacin patients had an SAE, with one case deemed unrelated to levofloxacin.

48. According to the Company's SEC filings, in September 2015, Cempra initiated two Phase 2 studies of the effectiveness of solithromycin as a treatment for chronic obstructive pulmonary disease ("COPD") and non-alcoholic steatohepatitis ("NASH"). The Company enrolled four patients in the Phase 2 COPD trial. During the Class Period and shortly after the COPD trial was initiated, three out of the four patients (75%) exhibited patterns of DILI. One patient experienced clinical hepatitis and was discontinued from treatment. One of the other two other patients exhibiting DILI continued to show symptoms of liver injury even after treatment discontinuation.

49. During the Class Period, and as a direct result of Defendants' access to information regarding liver toxicity data in the COPD trial, the Company amended the protocol for the Phase 2 NASH trial (six patients enrolled) to reduce dosage from 400 mg of solithromycin daily, to 200 mg daily, with the option of further reducing the dose to 200 mg three times per week. While the Company made this amendment in the event patients taking the drug in the NASH trial experienced elevated liver enzymes, one patient in the trial had exhibited a pattern of DILI. Defendants reported the NASH trial protocol amendment at the website ClinicalTrials.gov and to investors during the Company's September 30, 2016

conference call, but they failed to disclose to investors that they had reduced the dosage in the NASH trial because of DILI observed in the COPD trial.

50. The Phase 3 clinical trial of solithromycin taken orally for the treatment of CABP (the "Solitaire-Oral trial") was conducted between December 2012 and October 2014, while the IV Phase 3 trial (the "Solitaire-IV trial") was conducted between November 2013 and September 2015. These studies evaluated the safety and efficacy of oral and IV solithromycin compared to moxifloxacin, a fluoroquinolone which is considered the most potent drug for CABP. The primary objective and endpoint of these trials was to show statistical non-inferiority compared to moxifloxacin in early clinical response rate in the intent-to-treat population. The secondary objectives included showing safety and tolerability of solithromycin compared to moxifloxacin.

51. The Solitaire-Oral trial enrolled 860 adult patients with CABP. Four hundred twenty-six patients were randomized to receive either 400 mg of moxifloxacin on days one through seven or 800 mg of solithromycin orally on day one, followed by 400 mg on days two through five, followed by a placebo on days six and seven. The Solitaire-IV trial enrolled 863 adult patients with CABP. Four hundred thirty-four patients were randomized to solithromycin and 429 were randomized to moxifloxacin. All patients received the IV study drug on day one, and could be switched to the oral study drug if certain criteria were met, or remain on IV for seven once-daily doses. Patients randomized to moxifloxacin received 400 mg IV or orally; those randomized to solithromycin received 400 mg IV, 800

mg orally on the first oral dosing day, and 400 mg orally on subsequent days for a total of seven oral doses.

52. On January 4, 2015, Cempra issued a press release announcing positive topline results from its Solitaire-Oral trial. The Company reported that it met the primary and secondary objectives of statistical non-inferiority compared to moxifloxacin. With regard to safety, the Company reported that SAEs occurred with equal frequency in both arms (<7% of patients), and no SAEs were considered study drug related. Cempra also noted that "asymptomatic, reversible ALT elevation" was observed in both treatment arms. It stated that Grade 3 ALT, (defined as greater than 3-8 times the upper limit of normal, or "ULN") occurred in 2.1% of moxifloxacin patients and 4.6% of solithromycin patients, and Grade 4 ALT elevation (>8xULN) occurred in 1.2% of moxifloxacin patients and 0.5% of solithromycin patients.

53. Cempra further reported in the January 4, 2015 press release that no patient in either arm of the study developed treatment emergent elevation of both ALT and bilirubin, defined by Hy's Law criteria. Hy's Law is an observation of altered liver function and is an indicator that a drug could cause serious liver injury. Specifically, Hy's Law cases are the combined finding of aminotransferase ("AT") elevation accompanied by impaired hepatic function (bilirubin elevation >2xULN), in the absence of evidence of biliary obstruction (*i.e.*, significant elevation of ALT) or some other explanation of the injury (*e.g.*, viral hepatitis or alcohol hepatitis), which represents a signal of a potential for a drug to cause severe DILI. A Hy's Law case predicts severe liver injury at a rate of at least 1/10 of the rate of Hy's Law

cases. Thus, 1 case in 1,000 suggests severe injury at a rate of 1/10,000. In order to detect such a rate, a study of at least 3,000 patients is needed, with comfort that no Hy's Law cases will result if no cases of Hy's Law are observed in the study. Importantly, according to the FDA's Guidance for Drug-Induced Liver Injury, the failure to find a case of Hy's Law does not imply that a drug with AT elevations is free of a risk of severe DILI.

54. On October 16, 2015, Cempra issued a press release reporting positive topline results from the Solitaire-IV trial. Cempra announced that solithromycin met the FDA's primary and secondary objectives of statistical non-inferiority compared to moxifloxacin. With respect to safety, Cempra disclosed that fatalities occurred with similar frequency in both arms, with five patients on the solithromycin arm (1.2%) and seven patients on the moxifloxacin arm (1.6%) dying due to pneumonia or its complications during the study period. It noted that more treatment-related adverse events were observed with solithromycin (34.3%) compared to moxifloxacin (13.1%), a difference Cempra attributed largely to the occurrence of infusion site reactions. According to Cempra, the reactions were primarily of mild or moderate severity in solithromycin patients, and infusion site pain is a known side effect of intravenous macrolides as a class and is not typically noted with fluoroquinolones. Cempra reported that 2.1% of IV solithromycin patients (9 out of 432) discontinued study drug dosing due to the adverse infusion-related events.

55. In an October 22, 2015 press release, Cempra also reported SAEs occurred in 6.9% of solithromycin patients and 5.4% of moxifloxacin patients. Among all SAEs, only three were considered related to the study drug, all of which were allergic reactions (two

solithromycin patients and one moxifloxacin patient). Cempra stated that study drug discontinuation due to non-infusion-related adverse events was comparable between study arms (3.5% of solithromycin patients and 3.8% of moxifloxacin patients). Cempra noted that ALT elevation was observed in both treatment arms, with Grade 3 ALT elevations (>3-8xULN) occurring in 8.2% of solithromycin patients and 3.5% of moxifloxacin patients and Grade 4 ALT elevations (>8xULN) occurring in 0.7% of solithromycin patients and 0.5% of moxifloxacin patients. Treatment-emergent ALT elevations were generally asymptomatic, reversible and not associated with increased bilirubin. Cempra stated that no solithromycin patient met Hy's Law criteria of concurrent ALT and bilirubin elevations post-baseline.

56. Following the release of the data from the Solitaire-IV trial, Cempra told investors it was proceeding with solithromycin's NDA submission to the FDA for the treatment of CABP, which it expected to complete during the first half of 2016. Cempra also anticipated submitting a marketing authorization application (or "MAA") to the European Medicines Agency ("EMA") within a short period of time after its planned filing of the NDAs for solithromycin with the FDA.

57. While its studies were ongoing, FDA rules and regulations required Cempra, as sponsor, to promptly report instances of SAEs. 21 C.F.R. §312.32(c)(1)(i)(A). An example provided by the FDA of a serious and unexpected suspected adverse reaction that must be reported includes a single occurrence of a hepatic injury, as such occurrences are uncommon and known to be strongly associated with drug exposure. According to the FDA's Expedited Safety Reporting rules, DILI is the adverse event that most frequently leads to regulatory

action on drugs and requires expedited reporting within 15 days of the event. Accordingly, Cempra and the Individual Defendants became aware ***virtually immediately*** of any instances of DILI that occurred during the studies. Thus, when the Class Period began, Defendants would have been aware of the cases of at least eight patients taking the drug in the Phase 3 CABP studies who experienced liver toxicity and solithromycin-induced liver injury, and, prior to and during the Class Period, at least six patients who suffered liver toxicity and solithromycin-induced liver injury during the Company's Phase 1 and 2 studies.

DEFENDANTS' MISLEADING STATEMENTS AND MATERIAL OMISSIONS

58. On July 7, 2015, Cempra issued a press release announcing that it had completed the enrollment for the global Solitaire-IV Phase 3 trial of solithromycin in adult patients with moderate to moderately severe CABP. Cempra also announced that the study's top-line efficacy and safety data were on track to be announced by the end of the year. Cempra's announcement also quoted defendant Fernandes' statement:

> "***We remain on track to announce the top line results before year-end 2015. We believe that these results, coupled with our successful Solitaire Oral results, which we announced in January, will provide a compelling clinical data set in our solithromycin NDA submission***, expected in 2016. Additional clinical investigations are continuing including a Phase 3 urethritis study, as well as a solithromycin pediatric program."

59. On October 16, 2015, Cempra issued a press release and filed a Form 8-K with the SEC regarding positive top-line Phase 3 clinical results for IV solithromycin. These publications noted an observation of elevated ALT in both the solithromycin patients and the moxifloxacin patients, and stated: "***Treatment emergent ALT elevations were generally***

asymptomatic, reversible, and not associated with increased bilirubin. No solithromycin patient met Hy's Law criteria of concurrent ALT and bilirubin elevations post-baseline."

60. On October 16, 2015, following the issuance of the press release, Cempra held a conference call to discuss the positive top-line Phase 3 clinical results for IV solithromycin. During that call, the following exchange occurred between an analyst and defendants Fernandes and Oldach:

> RITU BARAL [Cowen & Company - Analyst]: Yes. And then the ALT ASG elevations, you mentioned in the press release that they were generally asymptomatic. Where there symptomatic patients in the 3X – or, sorry, Grade 3 or Grade 4?
>
> * * *
>
> OLDACH: Sure. We've gone through all of these cases and looked carefully at them. There were a few patients, for instance, that had infusion pain but no symptoms relatable to right upper quadrant or liver pain. But we want to be very careful about that. So before we say categorically absolutely none, we will be going back through their cases two more times before we declare that. ***But generally, no symptoms, no evidence of hepatic injury that was symptomatic or with bilirubin elevation. So that was just a cautionary statement on our part just so we could be absolutely certain. But our impression is none***.
>
> FERNANDES: And remember, the [data management committee] has seen each of these, you know, any significant ALT elevation, during the study and did not do anything.

61. On October 22, 2015, Cempra conducted its third quarter 2015 earnings conference call. Defendants Fernandes, Hahn and Oldach participated in the conference call. During Fernandes' opening remarks, she stated:

> Now let's discuss liver safety. Cath studies are conducted in patients with serious disease and underlying comorbidity, meaning they have other bad illnesses. Transient and reversible [alanine transaminase ("ALT")] elevation,

which is a liver enzyme increase, is a class-effective macrolide and this is also seen with almost all antibiotic classes, including agents commonly used for CABP, such as augmentin, Rocephin, and the respiratory fluoroquinolones like Avelox and Levaquin.

* * *

As one would expect, in both Phase 3 trials, these we saw some Grade 3 ALT elevation, and to a much lesser extent some Grade 4 ALT elevations. ***In almost all cases of ALT elevations among solithromycin recipients, these elevations occurred early, peaked on day four – remember, it is day one through seven – and their levels were typically declining by day seven, despite continued study drug dosing. These ALT increases were asymptomatic and resolved post treatment***.

No solithromycin recipient met Hy's Law criteria, defined as simultaneous ALT and bilirubin elevation – another liver factor – following dosing. There was no evidence of drug hypersensitivity reaction. For instance, one involving a combination of rash, fever, and ALT elevation, and other symptoms.

62. Later during the October 22, 2015 earnings conference call, defendant Fernandes and David Moore ("Moore"), Cempra's Executive Vice President and Chief Commercial Officer, made the following statements:

FERNANDES: So talking about macrolides and the ALT elevations relative to other macrolides, as you remember in the older study, we just had about the same as Moxifloxacin. And that is about the same as erythromycin and other macrolides. It all depends on the blood levels because as I mentioned, these drugs are excreted, metabolized by the liver. So you get more into the blood. It is going to go most to the liver. You're going to see more ALT increases.

Some drugs which don't make much of it in the blood, if they are not absorbed well, you are not going to see much changes. However, this change is expected. ***Now with the IV, yes, we saw a few more ALT [treat]. But again, they are all reversible***. In a real-life situation, unless there is a symptom, unless there is a problem, no one is even going to test it.

So when you get Z-Pak, no one takes your blood to see if you got an ALT increase. So the general data is not known. It is only on hospitalization where you would be doing this blood test.

So David, would you like to add anything to that?

MOORE: I would just like to underscore the fact that these ALT elevations that we have seen, in most cases, as Prabha said, have been on their way down with continued dosing by day seven. So we have not seen hepatic dysfunction in any patient due to the study drug in our Phase 3 program.

63. In addition, during the October 22, 2015 earnings conference call, the following exchange occurred between an analyst and defendant Fernandes:

RITU BARAL [Cowen & Company – Analyst]: Thanks for taking the question. Just a couple of questions that are related on the topic of the liver enzyme levels. One, can you give us a good idea at this point about how long it generally took for the ALT levels to resolve? Like number of days.

And, two: Prabha, if the ALT issue comes up with FDA, from what we understand there, it is mostly associated with the IV dosing as part of the last study. If it ended up being a handicap for the IV formulation, would you consider separating the indications from a regulatory perspective? Could you even do that? How do you look at the oral . . . ?

FERNANDES: No worries, Ritu. We have had these discussions internally and I don't believe there was any concern at all. But let me address it.

Firstly, as I mentioned and David mentioned, ***most of those ALTs came down during treatment. Many of them were down in two weeks. All of them were down in the three-week visit, the short-term follow-up visit. Okay. So there is no issue with that. So they all disappeared. That is why they are called reversible***. And both the oral and the IV study.

64. The following question and response statement by defendant Fernandes also occurred during the October 22, 2015 earnings conference call:

PRAKHAR VERMA [Stifel Nicolaus – Analyst]: This is Prakhar Verma on for Steve today. Thanks for taking my questions. I wanted to ask if there will be any opportunity to provide some further analysis of the liver

toxicity data, specifically the kinetics of patient-specific ALT responses over time? Or will we have to wait until you present the entirety of the data next year?

FERNANDES: We will present a combined data set sometime early next year, but not before a conference. We will certainly do that.

But let me again say: there is no liver toxicity. There is no hepatic toxicity. This was reversible ALT elevation and there has been no hepatic toxicity. So there is no evaluation of hepatic toxicity because we don't have any.

65. During the October 22, 2015 earnings conference call, the following question and response statement by defendant Fernandes also occurred:

BERT HAZLETT [Ladenburg Thalmann & Company Inc. – Analyst]: Thank you for letting me follow up. With regard to just some of the discussions that we have just been having, there has been discussions among investors about potentially comparing solithromycin's activity with the ketolides and [Ketek] in particular.

Could you just take a moment or two to describe what you see in terms of ALT elevations with solithromycin compared to what was seen with [Ketek] and what we know about that particular molecule? Thank you.

FERNANDES: Okay. That question is actually very dear to my heart because we thought we had put it in the coffin and nailed that thing shut a long time ago. But I will address that again.

* * *

What about those ALTs? Now, the ALTs described with [Ketek] was in clinical cases with sinusitis, bronchitis, PORT 1 pneumonia. [Ketek] was never tested in PORT 3, PORT 4 pneumonia. That was not the indication they have been going after. They have been going after community used for upper respiratory tract, not the serious illnesses. It would be unfair to compare ALT enzymes in [Ketek] tech versus our drugs.

And I already told you that [Ketek] ALT and our ALT have nothing to do with hepatic toxicity. ALT is not related to hepatic toxicity. And it is found with all drugs, including things like amoxicillin, augmentin, which we are actually giving tons of to children today.

66. On November 11, 2015, defendant Oldach sold 12,200 shares of his Cempra common stock for proceeds of over $351,000. Oldach failed in his duty, pursuant to the Company's Code of Conduct and the federal securities laws, to either disclose the material adverse facts concerning the safety profile of solithromycin stated in ¶¶81-83 before selling his stock, or to abstain from trading.

67. On November 19, 2015, the Company participated in the Jefferies Global Healthcare Conference. Defendant Fernandes spoke at the conference. During defendant Fernandes' opening remarks, she stated:

> Now when we announced some of the effects of the drug, we did mention liver enzyme increases. ALT increases. And you can see that with the intravenous, we had slightly more ALTs than in the oral, which is listed in the bottom, the Grade 3 and the Grade 4.
>
> Now ALTs go up if you had a very good lunch like Jefferies provided this afternoon, I wish I had measured everyone's ALTs because you would've seen ALTs go up in a lot of people. ALTs go up if the liver is a little taxed and is trying to digest and put things out there. And ALTs did go up because we give very high doses of drugs. In antibiotics you always get ALTs go up [sic] in many, many patients because you give high doses of antibiotics either intravenously or orally. And these ALTs go up.
>
> With macrolides especially, which are metabolized and excreted by the liver, you will see ALTs go up. And I've seen – I have given you numbers from the 6% with the intravenous azithromycin, which does not have significant blood levels, even with azithromycin, you see up to 6% go up. Now the patients they studied were not sick as our patients because azithromycin is used in minor infections.
>
> * * *
>
> ***Now the most important things, none of them had any symptoms. They were all reversible, and there was no bilirubin increase in any of these patients. And that is a key point. If you are on this drug, if you don't***

measure ALTs, you won't even know because there's no symptoms at all, in these patients, and they are all reversible.

Now we have actually put out data of the reversibility. People said, how fast does this reverse? So we have actually posted this data as an 8-K, and if you look at the purple stars on this, we look at the blood levels of ALTs and [aspartate transaminase ("ASTs")] on day one, day four, day seven, and then day 13. And you will see that while on study drugs, the patient is on study drug until day seven, even while on study drug, you can see the ALTs coming down. The liver gets used to it and no longer is it putting out the ALT enzymes.

You can see the same thing with ASTs. This is the reversible ALT and AST increases with no issues, [no] upper quadrant pain, no bilirubin increase and all reversible.

* * *

Now one more hiccup which happened was we talked about intravenous infusion reaction or pain at infusion site. Now you must remember these are very sick patients, and they are getting infusions for CABP. This is a clinical trial. ***We recorded every single thing the patient said. If there was redness, if there was itching, if there was tingling, anything minor was recorded***. And we are an honest company; ***we put out all the data***.

68. Between December 11 and December 15, 2015, defendant Oldach sold 10,000 shares of his Cempra common stock for proceeds of over $302,000. Oldach failed in his duty pursuant to the Company's Code of Conduct and the federal securities laws, to either disclose the material adverse facts concerning the safety profile of solithromycin stated in ¶¶81-83 before selling his stock, or to abstain from trading.

69. On January 7, 2016, Cempra filed its Prospectus with the SEC in connection with a public offering of common stock. Cempra sold a total of 4,166,667 shares of common stock in the offering at a price of $24.00 per share, for net proceeds to the Company of approximately $94 million. Defendants Fernandes and Hahn signed the Registration

Statement associated with the offering of Cempra common stock. The Company's January 7, 2016 Prospectus stated:

> Ketek is a macrolide antibiotic that the FDA approved in 2004 for the treatment of multi-drug resistant pneumococci and other CABP bacteria. Soon after release however, Ketek was found to cause reversible visual disturbances, exacerbate myasthenia gravis (a neurological disorder characterized by improper muscle regulation) and cause liver failure. These effects led the FDA to require the drug label for Ketek to include a strengthened warning section regarding specific drug-related adverse events and contributed to Ketek being withdrawn in 2007 for the treatment of all infections other than CABP. ***Through ongoing research, we have developed multiple ways to differentiate solithromycin from Ketek. Our research suggests these side effects may be caused by the pyridine moiety, which forms a part of the structure of Ketek. We have demonstrated that pyridine inhibits the action of nicotinic acid acetylcholine receptors that could result in the side effects caused by Ketek***. Solithromycin and older generation macrolides, including azithromycin and clarithromycin, that have been widely marketed do not have a pyridine component.

The Prospectus incorporated by reference the Company's alleged false and misleading July 7, 2015 and October 16, 2015 press releases, as set forth herein at ¶¶58-59.

70. On January 14, 2016, the Company participated in the J.P. Morgan Healthcare Conference. Defendant Fernandes spoke at the conference. During Fernandes' opening remarks, she stated:

> We would also like to show you some of the ALT results. This is the liver enzyme results. Macrolides that are excreted by the liver and are known to cause liver enzyme increases. You see the label from azithromycin, which is over there, that you see ALT increases. This does not give you the idea that this is hepatic toxic. To have hepatic toxicity, you have to have bilirubin increases, which causes – which shows damage to the liver cells. ***So, ALT increases plus bilirubin equals what is called [Hy's Law] and that means liver toxicity. We did not have any case in those numbers which you see there, which had both ALTs as well as bilirubin, not one in those entire two studies***.

So, we did not believe we had any side effects of liver toxicity in these particular patients.

I will also point out that they were asymptomatic, so there was nobody who would actually – know in real life during treatment that there was even any ALT increase. What is even more important is the gra[ph] at the very bottom. Even while on study drug, the ALT levels came down. So, if it was toxic, it would not come down, obviously it would stay up. So the liver learned to handle the drug, and then it came down. So we are very pleased with the safety of this as well as the efficacy.

71. On April 13, 2016, defendant Fernandes made the following statements at the Needham Healthcare conference:

Thank you. Yes, we will have an Advisory Committee. Almost surely we will have one. It is a new chemical entity. It's related to a drug called Ketek, so we do expect to have an Advisory Committee, ***but we have very clearly differentiated solithromycin from Ketek based on its mechanism of action and the reason for its adverse event***.

We have also shown the benefit of our drug used in monotherapy up against moxifloxacin, which is not a very safe drug, and we have a very good fully safety package for that. The benefit is obvious, that it needs to have an outpatient as well as hospital drug.

72. On May 2, 2016, Cempra conducted its first quarter 2016 earnings conference call. Defendant Fernandes participated in the call. Fernandes engaged in the following question-and-answer session with a Leerink Partners securities analyst:

PAUL MATTEIS [Leerink Partners – Analyst]: Okay. Thanks, Mark. That's helpful. And then maybe one more for Prabha.

I'm wondering what you expect to be the key points of discussion at an advisory committee? I mean, the Phase 3 data, they're clearly positive. You met the FDA end points. So maybe can you speak to any sources of controversy that you expect, if any, and to what degree prior experience with ketek may play in the discussion at an AdCom?

FERNANDES: ***Thank you. So we have worked very hard, together with safety experts, people who have consulted in the past with other***

companies, with the FDA and so on, very aware of liver safety. We do believe that on the ketek issue, we are over that hurdle, because we have shown the mechanisms as to why ketek was toxic.

However, we do have ALT. So our job is to make a comparison to the older macrolides like [erythromycin], [azithromycin], clarithromycin. All of them do have ALT increases. We have that too. But you must remember that every one of them came down, some of them even – most of them even while on study drug. So we don't believe there is a big concern.

73. On September 12, 2016, the Company participated in the Morgan Stanley Global Healthcare Conference. Defendant Hahn spoke at the conference. During the conference's question-and-answer session, Hahn made the following statement concerning the safety profile of solithromycin: "***What we see is what you expect from a macrolide: you expect ALTs to go up in the early days, and come back down. Even in continued therapy, we saw ALT levels coming right back down***."

74. During the September 12, 2016 Morgan Stanley Global Healthcare Conference, Hahn also responded to analyst inquiries as follows:

> ANDY BERENS [Morgan Stanley –Analyst]: Okay, great. One of the things that some investors have been concerned about is there was a similar macrolide called Ketek that had a pretty sordid past at the FDA. And some people worry that your drug may suffer because of that, both commercially as well as on the regulatory pathway to approval. Can you describe what happened with Ketek and how solithromycin differs?
>
> HAHN: Sure. So I'll start and talk about Ketek and some on the regulatory pathway concerns, and then Dave can talk about the commercial opportunity. Ketek was a previous-generation macrolide. It came out between the first generation that Dave talked about and now. And it did have some issues. We've done a lot of work characterizing what caused those issues. And, mechanistically, we looked at the molecule and saw what we think the bad actor is, and we did a lot of work to identify what that bad actor caused. And it was visual disturbance; it was exacerbation of myasthenia gravis; and it was liver toxicity.

All three were related to this same one bad actor called a pyridine. So if we look at solithromycin, we see that solithromycin doesn't have that bad actor on the molecule. It's a completely different structure. ***And in all of our trials – we have exposed over 2,000 patients and subjects over the years, and nobody has had any of those same types of issues that the folks had experienced with Ketek***. So we expect the questions will come up in the AdCom, but we don't – we think that we've adequately addressed those questions and we don't think there will be any issues.

* * *

ANDY BERENS [Morgan Stanley –Analyst]: Okay. Now, in both trials, you saw some elevation of the LFTs. It was all transit. How do you think the FDA is going to address that at the panel? Is that something they will ask the doctors to weigh upon?

HAHN: We think they will ask questions about those, most certainly. But we've gone through exhaustive work internally. We've hired independent consultants and advisors. We've got an AdCom advisory, or a consulting firm that brought in panels of experts and have gone through the data. ***What we see is what you expect from a macrolide: you expect ALTs to go up in the early days, and come back down. Even on continued therapy, we saw the ALT levels coming right back down***.

75. On September 30, 2016, the Company conducted a conference call for analysts and investors to discuss the interim results of an ongoing study of solithromycin in patients suffering from non-alcoholic steatohepatitis. Defendant Fernandes participated in the call. During the conference's question-and-answer session, defendant Fernandes made the following statement: "***I will remind you that in our CABP trial, which we presented to you, we have seen ALT increases even during the five to seven days of treatment which comes back***."

76. Also during the September 30, 2016 conference call, Defendants made the following statements regarding the change of dosage in the NASH trial:

DAVID OLDACH: ***When dosing solithromycin for longer durations, we've observed ALT elevation and since one of the goals of this trial to determine the optimal regimen for longer treatment period, we adjusted the dose to 200 milligrams daily for one week, followed by 200 milligrams three times a week***. The lower dose is supported by the mouse model and human PK data that suggest it might be efficacious. We hope to confirm this dosing regimen in the study and we are very excited with the therapeutic effects and safety profile we have seen thus far.

* * *

FERNANDES: That's why we decided to test it and then thirdly, ***we also wanted to show that solithromycin, of course, we believe it, is incredibly safe, even in the liver*** and this is the last straw which breaks the camel's back, right? ***So we wanted to test it in the worst case situation and tested it and we are now very comfortable with the drug***.

* * *

RITU BARAL [Cowen and Company– Analyst]: And was this the event [a patient taken off solithromycin in the NASH trial from days 29 to 45 due to ALT elevations] that triggered the change from 200 milligrams daily to the 200 milligrams three times a week in the protocol?

FERNANDES: No, we had already lowered the dose at that time. Because if you look at the modeling, the long-term dosage and our experience with it is saying that – that was more of a redundant study to show that one would be a long-term chronic dose and if you look at azithromycin, for instance with CF, in multiple doses for many weeks. It's dosed three times a week so it's not unusual for macrolides, which happen to linger intercellularly for long periods of time. That you should reduce the dose of chronic dosing.

* * *

So, Bert, I will remind you that we've seen ALT elevations in our CAB study and again, we knew at the end of this study because we got the results after the study was done. So it was not unexpected that we see it.

* * *

So all of the safety data – every human exposure is submitted as part of the law. We have submitted data until at the end of August and all data comes in, every part will be exposed. ***And we're very pleased with the safety of the***

drug. And it will provide a lot of benefits to patients in many categories now and so we're very pleased with it. We're proud to be able to submit this data.

77. On October 27, 2016, Cempra conducted its third quarter 2016 earnings conference call. Defendant Fernandes participated in the call and engaged in the following question-and-answer session with a Needham & Company securities analyst:

> DANIELLE BRILL [Needham & Company – Analyst]: Okay. Great. And then bringing it back to the ad-com and potential topics, obviously Ketek, as you mentioned, has been a concern. Can you just comment on what work was done earlier in development to address these concerns for the FDA?
>
> FERNANDES: Of course. I didn't plant this question, guys. This one, we've been working for ten years on this, right? So, we started this molecule, Ketek happened, and from day one we had to differentiate it. So, we showed that the pyridine on [telithromycin] was responsible for all those bad adverse events, including the hepatotoxicity.
>
> And the visual effect was really the canary in the coalmine because they saw in all their clinical trials and the same receptor in the eye and the same receptor in the liver, which has caused those effects. And we now have to differentiate the ALT increases that have shown to occur with all macrolides and all antibiotics because of the large dose and show what that is a result of. That is not a Ketek effect. And so we have spent a lot of time doing that sort of work. ***And our clinical trial data really shows that this has had a great deal of efficacy and all of those ALTs were reversible and asymptomatic, as you remember***.

78. As a result of Defendants' false and misleading statements during the Class Period, Cempra common stock traded at artificially-inflated prices.

79. Defendants' Class Period statements, set forth in ¶¶56-64, 66-68, 70, 72-76, were false and misleading when made. During the Class Period, and with respect to solithromycin's impact on the liver, Defendants misleadingly informed investors that: (a) observed increases in liver enzymes were not associated with symptoms of liver toxicity

and/or injury; (b) no patients taking the drug experienced liver dysfunction during the Company's clinical trials; (c) the Company observed no instances of liver toxicity in patients taking the drug; and (d) the Company had seen no data or reports of patients experiencing liver toxicity during the clinical trials. The true facts, which Defendants knew and/or had access to and failed to disclose to investors during the Class Period, were that in the completed Phase 3 CABP studies of solithromycin, at least eight patients taking the drug had in fact experienced liver toxicity and liver injury (all of whom also experienced significant increases in liver enzymes, including AST and ALT) (as set forth in ¶¶81-83, 85).

80. Defendants also made false and misleading statements during the Class Period concerning solithromycin's superior safety profile to Ketek, set forth in ¶¶65, 69, 71, 77, including that the Company had not seen in the clinical development of solithromycin any of the liver toxicity issues that had been seen during the Ketek clinical trials. The true facts, which Defendants knew and/or had access to and failed to disclose to investors during the Class Period, were that in the completed Phase 3 CABP studies of solithromycin, at least eight patients taking the drug had in fact experienced liver toxicity and liver injury (all of whom also experienced significant increases in liver enzymes, including AST and ALT). Further, in Phase 1 and Phase 2 studies that had been completed prior to the Class Period or were otherwise ongoing during the Class Period, at least six additional patients taking solithromycin had in fact experienced liver toxicity and liver injury (all of whom also experienced significant increases in liver enzymes, including AST and ALT) (as set forth in ¶¶81-83, 85).

DISCLOSURE OF THE TRUTH ABOUT THE SAFETY OF SOLITHROMYCIN

81. On November 2, 2016, the Company and the FDA posted on the FDA's website their respective briefing documents for the scheduled November 4, 2016 AdCom meeting. In the FDA's briefing document, it was disclosed that throughout the Company's Phase 1, Phase 2 and Phase 3 clinical studies, solithromycin safety data showed a significant signal for liver toxicity and liver injury.

82. The FDA's briefing document noted that in the safety databases in the Phase 2 and 3 trials and non-CABP studies, a pronounced hepatic injury signal was seen, including hepatocellular, cholestatic and hypersensitivity issues associated with the liver. The FDA briefing document noted that the liver-related adverse events seen with solithromycin during its clinical development program actually exceeded the pre-marketing hepatic signal seen with Ketek. The FDA briefing document stated that Cempra had presented no evidence to support any claim that solithromycin had a substantially lower potential to cause liver toxicity versus Ketek. With regard to the non-CABP studies, the FDA's briefing document disclosed that the Company had amended the Phase 2 NASH study protocol from a dosage of 400 mg daily to 200 mg daily with the option to decrease the dose to three times a week, because of patterns of DILI observed in the Phase 2 COPD trial. The FDA's briefing document further revealed that the Phase 2 COPD study had been halted pending modification (*i.e.*, reduction) of dosing due to patterns of DILI associated with exposure to solithromycin.

83. Attached to the FDA's November 2, 2016 briefing document was Dr. Mark Avigan's ("Dr. Avigan") memorandum analyzing the significant liver safety signal associated with solithromycin. Dr. Avigan is an Associate Director, Critical Path Initiatives & Hepatologist, for the FDA. Dr. Avigan was present during the November 4, 2016 Advisory Committee meeting and spoke during the meeting regarding solithromycin's side effects. In Dr. Avigan's memorandum, he disclosed details of at least eight cases of patients taking the drug in the Phase 3 CABP studies in which patients had experienced liver toxicity and solithromycin-induced liver injury. According to Dr. Avigan's memo, six of these patients in the Phase 3 CABP trials experienced liver toxicity and liver injury, as a result of taking the Company's drug. These instances of liver toxicity and liver injury occurred on or about the following dates: April 24, 2014, November 17, 2014, April 9, 2015, May 27, 2015, June 11, 2015 and June 24, 2015. Dates for two other patients' liver injuries were not provided by the FDA, but would have occurred prior to the Class Period because the primary completion dates for the two critical Phase 3 CABP studies (CE01-300 and CE-301), were October 2014 and July 2015, respectively. Dr. Avigan's memorandum also disclosed at least six additional patients who had suffered liver toxicity and solithromycin-induced liver injury during the Company's Phase 1 and Phase 2 studies. These studies were either completed prior to the Class Period or were ongoing during the Class Period. Pursuant to FDA rules and regulations (*i.e.*, 21 C.F.R. §312.32(c)(1)(i)(A) and the FDA's Expedited Safety Reporting rules), Cempra was aware ***virtually immediately*** of these instances of DILI that occurred during the studies.

84. As a result of the November 2, 2016 disclosures Cempra's common stock price dropped from the prior day's close of $18.65 per share to $7.30 per share, a decline of 61%, on higher-than-average volume of 20.8 million shares traded.

85. On Friday, November 4, 2016, the FDA AdCom hearing was held. Trading in Cempra's stock was halted on the NASDAQ for the full trading day. During the AdCom hearing, additional information regarding the drug's association with liver toxicity and liver injury was disclosed, including the broader extent of hepatocellular, cholestatic and hypersensitivity toxicity patterns. While the efficacy of solithromycin was unanimously supported by the AdCom panel, it also concluded by a vote of 12-1 that the risk of hepatotoxicity and liver injury had not been adequately characterized by Company.

86. Investors reacted negatively to the additional information regarding the drug's safety profile disclosed during the November 4, 2014 AdCom hearing. On Monday, November 7, 2014, Cempra's common stock price dropped again from the prior day's close of $7.55 per share to $6.85 per share, a decline of 9.3%, on higher-than-average volume of 13.6 million shares traded.

87. On December 5, 2016, *The Motley Fool* published an article entitled: "Biotech's Dumbest CEO Moves in 2016." The article led with a discussion of Cempra and the recent revelations of liver injury associated with solithromycin. In the article, the author observed: "***Not disclosing the potential liver issues before the FDA briefing documents [had been published] was a huge mistake as the 61% decline [in Cempra's stock price] after the FDA disclosure clearly showed***."

88. On December 29, 2016, Cempra announced that the FDA had issued a CRL for solithromycin. The FDA recommended an approximately 9,000-patient exposure study for solithromycin to appropriately assess the hepatotoxicity profile of the drug. As a result of the December 29, 2016 disclosure, Cempra's common stock price dropped again from the prior day's close of $6.10 per share to $2.60 per share, a decline of 57.4%, on higher-than-average volume of 21.4 million shares traded.

89. On February 28, 2017, Cempra announced it was reducing its workforce from 136 to 45 employees, a reduction of 67%, after reporting a loss of $118 million in 2016. Cempra also announced that it was conducting a review of strategic business options.

90. On March 28, 2017, Cempra announced that it was withdrawing its MAA seeking EMA approval of oral and intravenous formulations of solithromycin for the treatment of CABP in the EU. The Company noted that based on the 120 questions it received from the EMA, it believed that additional data would be required for approval in the EU. The Company added that the withdrawal of the EU application should allow Cempra to conserve considerable financial resources and align its strategy to provide additional data to both the EMA and the FDA.

DEFENDANTS' MOTIVE AND OPPORTUNITY TO DEFRAUD INVESTORS

91. Prior to the Class Period, Cempra repeatedly informed investors that the Company would need to continue to raise capital because the Company generated little revenue, had been suffering negative cash flow from inception, and needed substantial amounts of cash to complete the clinical development of solithromycin. Cempra's 2014

Form 10-K revealed the Company's expenses for drug development and clinical trials primarily resulted in net losses of $45 million and $61.6 million in 2013 and 2014, respectively. In 2013 and 2014, the Company obtained $54.4 million and $48.5 million in proceeds from follow-on offerings of common stock. Moreover, during these two periods, the Company expended $41.3 million and $62.5 million in research and development and informed investors that the Company would continue to spend heavily on research and development.

92. With little revenue for the foreseeable future and continued significant spending to support the research and development costs for solithromycin, Cempra's existence as a company was contingent on the amount of capital it could obtain through public offerings – funding that was largely dependent on the Company's stock price. As Cempra noted in its 2014 Form 10-K: "If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing discovery, development and commercialization efforts, and our ability to generate revenues and achieve or sustain profitability will be substantially harmed."

93. As a consequence, and following the false statements regarding the safety of solithromycin between July 2015 and November 19, 2015, Defendants conducted an additional follow-on offering of Cempra common stock to continue to fund the Company's operations. The offering took place in January 2016. As stated in Cempra's Prospectus Supplement Form 424B5, Defendants had to raise funds to:

> [F]und the U.S. launch of solithromycin for CABP, [to hire] additional commercial management personnel, engaging in pricing research and other market research, and to begin building our specialty antibiotic sales force, . . . fund our research and development activities, including continued clinical and regulatory development of solithromycin . . . .

94. According to the Company's 2015 Form 10-K, Defendants sold 4.17 million shares of Cempra common stock – at an artificially-inflated price of $24.00 per share – for total proceeds of $94 million in the January 2016 offering. This funding was critical for Cempra to continue its operations, as the Company continued to report increased losses in 2015 – indeed, more than $91.1 million. But for Defendants' intentional decision to misstate and withhold the actual safety profile of solithromycin in the CABP trials, the Company's Class Period stock price would have been substantially lower, and Cempra would have been unable to obtain the $94 million in essential funding.

95. The Company had expected to raise $175 million in the January 2016 offering, but was unable to do so. Thus, the Company conducted an "at-the-market" ("ATM") offering to continue to provide the Company working capital to make up the difference as it burned through cash. An ATM offering is a type of follow-on offering of securities that allows a publicly-traded company to raise capital over time. Specifically, between May 2016 and July 2016, inclusive, the Company sold an additional four million shares of common stock pursuant to the ATM offering for net proceeds of $75.1 million, making up the difference Cempra had anticipated raising in January 2016. But for Defendants' intentional decision to misstate and withhold the actual safety profile of solithromycin in the CABP trials, the Company's Class Period stock price would have been substantially lower,

and Cempra would have been unable to obtain the $75.1 million in additional and essential funding.

LOSS CAUSATION/ECONOMIC LOSS

96. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive investors and the market and a course of conduct that artificially-inflated the price of Cempra stock and operated as a fraud or deceit on Class Period purchasers of Cempra stock and call options by misrepresenting and omitting material information about the safety of solithromycin. When Defendants' prior misrepresentations and omissions were disclosed to the market, beginning on November 2, 2016, Cempra securities prices fell precipitously, as the prior artificial inflation came out of the price. As a result of their purchases of Cempra common stock and call options on common stock during the Class Period, Plaintiffs and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

97. Defendants' false and misleading statements, identified herein at ¶¶58-77, had the intended effect and caused Cempra's common stock and call options to trade at artificially-inflated levels during the Class Period.

98. As a direct result of the disclosures that began on November 2, 2016, and as detailed in ¶¶81-83, Cempra's common stock price suffered a significant decline. On November 2, 2016, the price of Cempra's common stock plunged 61% per share in response to the truth about the safety profile of solithromycin.

99. The disclosures on November 4, 2016, detailed in ¶85, also had a direct impact on Cempra's common stock and call option prices. The price of Cempra common stock fell 9% per share on November 7, 2016 in response to additional disclosures of the truth about the safety profile of solithromycin.

100. The declines in Cempra securities prices on November 2 and November 7, 2016 were a direct result of the nature and extent of Defendants' prior misstatements and omissions being revealed to investors and the market. The timing and magnitude of Cempra's securities prices negates any inference that the losses suffered by Plaintiffs and other members of the Class were caused by changed market conditions, macroeconomic or industry factors or Company-specific factors unrelated to Defendants' fraudulent conduct. On November 2, 2016, the NASDAQ was down less than 1% and the NASDAQ Biotechnology Index was down less than 2%. On November 7, 2016, the NASDAQ was up by 2% and the NASDAQ Biotechnology Index was up 4%.

101. The economic losses suffered by Plaintiffs and other members of the Class were a direct result of Defendants' fraudulent scheme to inflate Cempra common stock and call option prices and the subsequent decline in the value of the common stock and call options when Defendants' prior misrepresentations and omissions were revealed.

APPLICABILITY OF THE PRESUMPTION OF RELIANCE

102. Plaintiffs and the Class are entitled to a presumption of reliance pursuant to *Basic Inc. v. Levinson*, 485 U.S. 224 (1988), and the fraud-on-the-market doctrine. During the Class Period, Cempra stock traded in an efficient market on the NASDAQ and the

material misstatements and omissions alleged herein would induce a reasonable investor to misjudge the value of Cempra stock. Further, without knowledge of the misrepresented or omitted material facts, Plaintiffs and other members of the Class purchased or acquired Cempra stock between the time Defendants misrepresented and failed to disclose material facts about solithromycin and the time the true facts were disclosed. Accordingly, Plaintiffs and other members of the Class relied, and are entitled to have relied, upon the integrity of the market for Cempra common stock, and are entitled to a presumption of reliance on Defendants' materially false and misleading statements and omissions during the Class Period.

103. Plaintiffs and the Class are also entitled to a presumption of reliance under *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972), because the claims asserted herein against Defendants are predicated upon omissions of material fact for which there was a duty to disclose.

NO SAFE HARBOR

104. Defendants' false and misleading statements during the Class Period were not forward-looking statements and/or were not identified as such by Defendants, and thus did not fall within any "Safe Harbor." In addition, the purported cautionary language that accompanied Defendants' false and misleading statements was inadequate and was ineffective to shield those statements from liability.

CLASS ACTION ALLEGATIONS

105. Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Cempra common stock during the Class Period. Excluded from the Class are Defendants and their immediate families, directors and officers of Cempra and their immediate families, and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

106. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. During the Class Period, Cempra had more than 48 million shares of stock outstanding, owned by hundreds or thousands of persons.

107. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class that predominate over questions that may affect individual Class members include:

(a) Whether the Exchange Act was violated by Defendants;

(b) Whether Defendants omitted and/or misrepresented material facts;

(c) Whether Defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) Whether Defendants knew or recklessly disregarded that their statements were false and misleading;

(e) Whether the price of Cempra common stock was artificially-inflated; and

(f) The extent of damage sustained by Class members and the appropriate measure of damages.

108. Plaintiffs' claims are typical of those of the Class because Plaintiffs and the Class sustained damages from Defendants' wrongful conduct.

109. Plaintiffs will adequately protect the interests of the Class and have retained counsel who are experienced in class action securities litigation. Plaintiffs have no interests which conflict with those of the Class.

110. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

COUNT I
For Violation of §10(b) of the Exchange Act and Rule 10b-5
Against All Defendants

111. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein. Count I is brought pursuant to §10(b) of the Exchange Act, 15 U.S.C. §78j(b), and Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5.

112. During the Class Period, Cempra, through its officers, management and agents, including Defendants Fernandes, Hahn and Oldach, made or were responsible for the statements as set forth in ¶¶58-77, which they knew or recklessly disregarded were misleading in that they failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

113. Defendants and the Company's officers, management and agents directly and indirectly, by the use of means and instrumentalities of interstate commerce, the mails and/or the facilities of a national securities exchange: (a) employed devices, schemes and artifices to defraud; (b) made misleading statements and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or (c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon Plaintiffs and others similarly situated in connection with their purchases of Cempra common stock during the Class Period. All Defendants are sued as primary participants in the wrongful and illegal conduct charged herein and as controlling persons as alleged below.

114. Defendants and the Company's officers, management and agents did not have a reasonable basis for their alleged false statements and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Cempra common stock during the Class Period.

115. Cempra is liable for all materially false and misleading statements and omissions made during the Class Period, as alleged above, including the false and misleading statements made by the Company's officers and agents, as alleged above, as the maker of such statements and under the principle of *respondeat superior*.

116. Defendants and the Company's officers, management and agents, individually and in concert, directly and indirectly, engaged and participated in a continuous course of conduct to conceal adverse material information about solithromycin.

117. The allegations above establish a strong inference that Cempra, as an entity, acted with corporate scienter throughout the Class Period, as its officers and agents had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth because they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and omissions were done knowingly or with recklessness, and without a reasonable basis, for the purpose and effect of concealing the truth about solithromycin and clinical development of the drug. By concealing these material facts from investors, Cempra's share price was artificially-inflated during the Class Period.

118. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and disclose such facts, even though such facts were available to them. Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing the truth about the safety of solithromycin and artificially inflating the price of Cempra common stock.

119. Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Cempra common stock. Plaintiffs and the Class would not have purchased Cempra common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements and omissions.

120. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their purchases of Cempra common stock during the Class Period.

COUNT II
For Violation of §20(a) of the Exchange Act
Against All Defendants

121. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein. Count II is brought pursuant to §20(a) of the Exchange Act, 15 U.S.C. §78t(a).

122. Defendants Fernandes, Hahn and Oldach acted as controlling persons of Cempra within the meaning of §20(a) of the Exchange Act. Cempra controlled all of its employees and defendants Fernandes, Hahn and Oldach. By virtue of their high-level positions, and their ownership and contractual rights, participation in and awareness of the safety profile of solithromycin, as well as their intimate knowledge of the false statements and omissions made by the Company and disseminated to the investing public, defendants Fernandes, Hahn and Oldach had the power to influence and control and did influence and control, directly or indirectly, the Company's decision-making, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. Defendants Fernandes, Hahn and Oldach participated in the conference calls with investors and analysts, described herein at ¶¶60-65, 67, 70-77, and/or prepared and approved the Company's SEC filings and press releases, described herein at ¶¶58-59, 69, alleged by Plaintiffs to be misleading.

123. In particular, Defendants had direct and supervisory involvement in the Company's day-to-day operations and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same. By reason of such conduct, Defendants are liable pursuant to §20(a).

124. As set forth above, Defendants each violated §10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, Defendants are liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of Cempra common stock during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for relief and judgment, as follows:

A. Determining that this action is a proper class action, and certifying Plaintiffs as Class Representatives under Federal Rule of Civil Procedure 23 and Plaintiffs' counsel as Class Counsel;

B. Awarding compensatory damages in favor of Plaintiffs and the other members of the Class against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' violations of the federal securities laws, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such equitable, injunctive or other and further relief as the Court may deem just and proper, including, but not limited to, rescission.

JURY DEMAND

Plaintiffs hereby demand a trial by jury.

DATED: August 16, 2017

s/ L. Bruce McDaniel
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CERTIFICATE OF SERVICE

I hereby certify that on August 16, 2017, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the attached Electronic Mail Notice List, and I hereby certify that I caused to be mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on August 16, 2017.

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Manual Notice List

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- (No manual recipients)